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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,757	09/15/2003	Michael S. Williams	9362-3	1920

20792 7590 08/18/2006

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EXAMINER	
LIN, JAMES	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,757	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Jimmy Lin	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *4,5,11,14,18-30,34,41 and 44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-10,12,13,15-17,31-33,35-40,42,43 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/5/04, 5/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on 5/16/06 is acknowledged. The traversal is on the ground(s) that examining Groups I-III would not create an undue hardship. This is not found persuasive because a serious burden exists in the differing issues involved with determining the patentability of the unrelated method of Group II and the product claims of Group III.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 4-5, 11, 14, 18-30, 34, 41, and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/2/06.

Priority

3. The provisional 60/426,125 has been reviewed. The Examiner has found that the provisional shows support for at least the independent claims 1 and 31. The provisional, however, does not seem to show support for a non-erodible polymer.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-2, 6-10, 13, 15-16, 32, 35-40, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Igaki et al. (WO 200243799) (with U.S. Publication 2003/0104030 as the evidence of translation).

Igaki discloses a method of impregnating a stent with a pharmacological agent (abstract), the method comprising:

immersing a stent comprising a polymeric material in a mixture of a carrier fluid and a pharmacological agent [0052];

pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to cause the carrier fluid and pharmacological agent to at least partially penetrate the polymeric material [0057];

removing the pressure such that the carrier fluid diffuses out of the polymeric material [0062] and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material [0011].

Claim 31: The stent is placed in a pressure vessel 27 [0057] and the polymer can be formed only on the surface of the stent [0067]. The pressure vessel is set to a pressure between 7.38-24 MPa [0058].

Claims 2,6,32,36: Supercritical carbon dioxide is the carrier fluid [0052]-[0058].

Claims 7,9,37,39: Ethanol can be used as a co-solvent [0053].

Claims 8,38: The carrier fluid is used to cause the polymer to become swollen [0063], thereby altering the diffusion coefficients of the polymeric material.

Claims 10,40: The intraluminal prosthesis is a stent (abstract).

Claims 13,43: The polymer can be formed only on the surface of the stent [0067].

Claims 15,16: The pressure is controlled in the step of removing pressure [0062].

Claim 35: The pressure vessel can be pressurized with carbon dioxide [0057].

6. Claims 1-2, 6-9, 12-13, 15, 31-32, 35-39, 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Greiner (EP 0405284).

Greiner discloses a method of impregnating a catheter with a pharmacological agent [0001], the method comprising:

immersing a catheter comprising polymeric material in a mixture of a carrier fluid and a pharmacological agent (col. 1, lines 1-7);

pressurizing the mixture of carrier fluid and pharmacological agent for a time sufficient to cause the carrier fluid and pharmacological agent to at least partially penetrate the polymeric material;

removing the pressure such that the carrier fluid diffuses out of the polymeric material and such that an amount of the pharmacological agent remains elutably trapped within the polymeric material (col. 3, line 50 – col. 4, line 6).

Claim 31: The catheter can be placed in a reactor with a pressure of 1200 psig (Example 1) and the polymer can be formed on the catheter before impregnation (col. 4, lines 45-47).

Claims 2,6,32,36: Supercritical carbon dioxide can be the carrier fluid (col. 3, lines 17-27).

Claims 7,9,37,39: Ethanol can be used as a co-solvent (Example 2).

Claims 8,38: The carrier fluid causes the polymer to swell, thereby increasing the diffusion of the pharmacological agent (col. 3, lines 27-29).

Claims 12,42: The polymer can be non-erodible, such as silicone rubbers (col. 2, line 4 – col. 3, line 2).

Claims 13,43: The polymer can be formed only on the surface of the catheter (col. 4, lines 45-47).

Claims 15,16: The pressure is controlled in the step of removing pressure (col. 4, lines 4-6).

Claim 35: The pressure vessel can be pressurized with carbon dioxide (Example 1).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 3 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki '799, as applied to claims 2 and 32 above, in view of Edwards et al. (U.S. Patent 6,670,398).

Igaki is discussed above, but does not teach the use of everolimus as the pharmacological agent. However, Edwards teaches everolimus is a therapeutic drug that can be used to suppress the transplant recipient's immune response against the transplanted organ or tissue (col. 2, lines 3-10). Everolimus can be coated onto a stent (col. 21, lines 8-39). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have impregnated everolimus as the particular pharmacological agent onto the stent of Igaki with a reasonable expectation of success because Edwards teaches that it is suitable to administer everolimus using a stent and because one would have been motivated to do so in order to provide stent for use in organ or tissue transplant.

9. Claims 3 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner '284, as applied to claims 2 and 32 above, in view of Edwards et al. (U.S. Patent 6,670,398).

Greiner is discussed above, but does not explicitly teach the use of everolimus. However, Edwards teaches everolimus is a therapeutic drug that can be used to suppress the transplant recipient's immune response against the transplanted organ or tissue (col. 2, lines 3-10). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used everolimus as the particular pharmacological agent with a reasonable expectation of success because Greiner is open to the use of other pharmacological agents (col. 4, lines 7-10), because Edwards teaches that everolimus is a suitable pharmacological agent, and because one would have been motivated to do so in order to provide a catheter for use in organ or tissue transplant.

10. Claims 17 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Igaki '799, as applied to claims 1 and 31 above, in view of Ragheb et al. (U.S. Patent 6,299,604).

Igaki is discussed above. Igaki teaches herapin as an example of a pharmacological agent [0050], but does not explicitly teach using a radiopaque material. However, Ragheb teaches that

a radiopaque material is a suitable alternative to herapin for use in the vascular system. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a radiopaque material as the particular pharmacological agent with a reasonable expectation of success because Ragheb teaches that radiopaque materials are suitable pharmacological agents that can be used in the vascular system.

11. Claims 17 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner '284, as applied to claims 1 and 31 above, in view of Ragheb et al. (U.S. Patent 6,299,604).

Greiner is discussed above, but does not explicitly teach the use of a radiopaque material. However, Ragheb teaches that a radiopaque material is a pharmacological agent that can be used in the vascular system. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a radiopaque material as the particular pharmacological agent with a reasonable expectation of success because Greiner is open to the use of other pharmacological agents (col. 4, lines 7-10) and because Ragheb teaches that radiopaque materials are suitable pharmacological agents.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1, 2, 6, 7, 9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-47, 122-129, and 150-157 of U.S. Patent No. 6,932,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '930 fully encompasses the instant claims.

14. Claims 31-32, 36-37, and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-47, 122-129, and 150-157 of U.S. Patent No. 6,932,930 in view of Greiner '284. '930 does not teach placing the intraluminal prosthesis into a pressure vessel and pressurizing the vessel. However, Greiner teaches that such is obvious in the art.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mehta et al. (U.S. Publication 2002/0051845) teaches a method of impregnating a stent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902. The examiner can normally be reached on Monday thru Thursday 8 - 5:30 and Friday 8 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/8/06

TIMOTHY MEEKS
SUPERVISORY PATENT EXAMINER